

Page 1 of 3

**COPY**

## BioLife Plasma Services

## Informed Consent for Automated Plasmapheresis

DONOR NAME: Green Joan C PDN A 16236700  
Last First Middle Initial

BioLife Plasma Services L.P. is a medically supervised, licensed plasmapheresis center involved in the collection of plasma for medical purposes. A plasma donor can donate plasma up to two times in any seven-day period and there must be one or more days between these two donations. Attempting to donate more frequently will disqualify you as a donor and you will no longer be able to donate plasma. You must not donate for eight weeks after donating one unit of whole blood or 16 weeks after donating a double red blood cell donation. You should participate in one plasma donation program at a time and should not donate plasma or platelets at another facility while participating in our program. A medical interview, examination and laboratory testing will precede each plasmapheresis procedure to determine your acceptability to undergo the procedure.

The automated plasmapheresis procedure uses a specially designed system, which separates the plasma from the blood cells. The procedure requires a needle puncture into your vein and connection of the needle to the sterile tubing on the automated machine. You will remain connected to the machine for the entire procedure (approximately ½ hour to 1 hour). A portion of your blood will be withdrawn through the needle and mixed with an anticoagulant solution to prevent clotting of your blood during the procedure. The blood is separated into its two main parts, that is, plasma and red blood cells. The plasma is collected in a separate container. The red cells, mixed with an anticoagulant solution, are returned to your vein using the same needle. Several draw-and-return cycles are required to collect a specific amount of plasma determined by your weight. Sterile normal saline (a 0.9 % salt solution) will be given through the needle to partially replace the volume removed. Once the needle is removed, you will be asked to apply pressure with a gauze pad over the vein. Tape, or other wrapping material, will then be placed over the vein. This process will be performed at one sitting.

There is a remote risk of air entering your body while your cells are being returned. For your protection, air detectors continuously monitor the collection system for the presence of air. If air were detected, the machine would automatically turn off. Although a small amount of air would probably cause no harm, a large amount could cause a severe or even fatal reaction. However, this has never occurred during automated plasmapheresis.

Additional potential risks exist in a plasmapheresis procedure, which you should consider carefully before consenting.

1. Low blood pressure, possible nausea or vomiting, lightheadedness, feeling of weakness, or rapid breathing may develop due to anxiety or changes in blood volume.
2. Allergic reactions such as flushing, itching, hives, abdominal cramps, difficulty breathing, chest pain, and/or bronchospasm may occur, but are rarely life threatening.
3. A very small percentage of donors actually faint and experience convulsive seizures.
4. A hematoma (bruise) or pain due to nerve irritation may occur at the venipuncture site. Rarely, local skin infection or inflammation of the vein may also develop.
5. Very rarely, a small volume of your red blood cells may be ruptured during the procedure resulting in a release of hemoglobin to your bloodstream, which then is excreted in the urine causing urine discoloration for a short period of time. To help prevent this event, the machine continuously monitors for changes in plasma color and if significant, an alarm sounds and the procedure stops automatically. The red cells may not be returned to you.
6. The sterile saline solution may cause chills due to the cool room temperature.
7. The anticoagulant solution used may cause a tingling sensation of the fingers or lips. If this should happen, you should inform your technician immediately so he/she may adjust the procedure accordingly.

**BioLife Plasma Services**

**Informed Consent for Automated Plasmapheresis**

Your donation will be monitored by experienced technicians, but if you experience any discomfort, inform the technician. Occasionally, technical reasons may prevent the return of your red blood cells. This is no more serious than donating a unit of whole blood and simply means that you may be deferred from donating plasma or whole blood for a period of eight weeks.

Donors participating in the program on a regular and/or prolonged basis may experience changes in their hematocrit and/or serum protein content. These blood tests are monitored by the center at regular intervals. Significant changes in these or other tests will be noted by the reviewing medical staff and may need temporary deferment or permanent removal from the program.

You, as the prospective donor, do at this time or any time in the future, have the opportunity to ask any questions concerning the procedures. You also have the opportunity to refuse to participate before a consent form is signed. Furthermore, you, as a prospective or active donor, are free to withdraw your consent and to discontinue participation in the Plasmapheresis program at any time.

 **COPY**

THIS DOCUMENT CONTAINS PROPRIETARY INFORMATION.  
IT MUST NOT BE REPRODUCED OR DISCLOSED TO OTHERS  
WITHOUT PRIOR WRITTEN APPROVAL.

A16236700 -

## BioLife Plasma Services

## Informed Consent for Automated Plasmapheresis

Having been informed of the above, in writing and verbally, and having been given an opportunity to ask questions pertaining to the program, I voluntarily consent to participate in the plasmapheresis program.

I further agree to carefully follow the plasmapheresis center's instructions regarding care of the plasmapheresis needle site following the procedure. These instructions specifically include the following:

1. Leave the bandage in place for at least 2 hours after donation. Do not loosen or tighten the bandage during that period.
2. Do not touch or pick at the area where the needle had been inserted.
3. Keep the needle puncture site clean.
4. Do not wash the venipuncture site for at least 2 hours after donation.
5. Do not replace the same bandage. If a new bandage is needed, use a clean one.
6. After the donation, any trouble at the venipuncture site (bleeding, pain, redness, itching, bruising, swelling, rash, pus accumulation) must be shown to the center manager, assistant manager or physician as soon as it appears, when the center is open. You should contact your own physician or local emergency room at your discretion.

I have read and acknowledge the educational material entitled "AN IMPORTANT MESSAGE TO ALL DONORS ABOUT INCREASED RISK BEHAVIORS." I have read and acknowledged the "TESTING INFORMATION AND CONSENT FORM." I have been given an opportunity to ask questions to the Center Physician or Medical Supervisor pertaining to any of this information.

I understand I will receive a fee for the time and commitment required for donation. I also understand that the plasma will be used to manufacture or develop products for commercial sale. However, should I be unable to donate because of my health--or any reason at all--I will not be entitled to any fee. I also understand that I am free to withdraw from this program at any time, and that the plasma center staff has the right to accept or reject me--for any reason--as a donor of plasma.

I understand that the center records, including donor records, are subject to inspection by FDA and other regulatory agencies.

Having been informed of the criteria for donor acceptability, I am unaware of any condition or circumstance that would preclude me from donating blood or plasma at this time.

Donor's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

2-26-09

Center Physician/Medical Supervisor: \_\_\_\_\_

Date: \_\_\_\_\_

2-26-09